



Guidelines

Responsibility and process to ensure legal compliance of promotional material produced by Roche's Pharmaceutical Business

1. Objective:

The Business and Marketing organization must fully exploit the data available on the products and communicate them in a clear and effective way while respecting the voluntary and statutory rules.

2. Background:

All promotional material must comply with national laws and regulations, and industry codes on pharmaceutical promotion and fair competition. Over time, rules have been tightened and adherence more closely watched by authorities and competitors.

The purpose of this guideline is to establish a process to ensure that all PB promotional material is compliant with the existing rules by clearly defining the responsibility for the final clearance of materials and by regulating the approval process within teams. Promotional material is any product communication directed to external audiences (general public, health care professionals, investors etc.) including the internet.

3. Responsibility for compliance

Business Directors have final responsibility for ensuring that all promotional materials used by their teams are compliant with local and international industry codes and national laws and regulations. They are responsible for the implementation of the approval processes within their teams.

4. Roles and responsibilities within Lifecycle teams

LCL: The development and approval process for promotional materials is organised within each Lifecycle Team under the responsibility of the Lifecycle Leader. He/She ensures that all necessary clearances are obtained, including from involved affiliates if applicable, before presenting to the Business Director for final "sign-off". The Lifecycle Leader also organises that the approval process for each material is formally documented on the appropriate form and the document stored as per point 5 below.

IBL: The International Business Leader is responsible that the key product messages defined in the product strategy are effectively communicated in our promotional materials. He/She ensures that all competitor statements comply with regulations including anti-competitive laws. In the event of affiliate involvement, the IBL ensures the previous clearance by the responsible person in the affiliate.

IMM: The International Medical Manager is responsible for data accuracy and consistency and for fair balance of statements. He/She clears material for these aspects.

GRL: The Global Regulatory Leader or the regulatory EU partner reviews the label conformity with the EU SPC (if available) of promotional materials which are implemented directly by PB (and not through affiliates).

Disagreements within the Lifecycle Team are escalated to the Lifecycle Leader and eventually to the Business Director for final decision.

5. Process documentation and record retention

The process of clearance and approval of promotional materials must be formally documented on the form created for this purpose. The completed form and any supporting documentation like e-mails have to be stored (in hard copy or electronically) during 2 years by the lifecycle team. In case of a pending legal case this period can be extended based on a request from the legal department.

6. Affiliate involvement

Any promotional activity being carried out in a specific country is subject to the national laws and regulations and needs to be cleared for its compliance by the local Roche affiliate. Responsibility and process within affiliates is as defined by the affiliate. The GM ensures adequate resources to allow for a speedy process.

This applies in particular to medical events and all promotional materials used (booth, give-aways, reprints etc.) Internet publications and advertisements in publications with international distribution require special attention.

7. Legal support

Whereas compliance with rules and processes is responsibility of the business areas, the Corporate Legal Department is available for support (including training) and should be contacted in case of doubts. For US matters the competence is with the Roche Nutley Law Department.

8. Approval

These guidelines were approved on June 14th, 2004, and came into effect the same date.